IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SCHERING CORPORATION and MSP SINGAPORE COMPANY LLC, Plaintiffs, v. GLENMARK PHARMACEUTICALS INC., USA and GLENMARK PHARMACEUTICALS LTD., Defendants.	Civil Action No. 07-cv-1334 (JLL)(ES) **FILED ELECTRONICALLY** Oral Argument Requested

GLENMARK'S STATEMENT OF MATERIAL FACTS NOT IN DISPUTE IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF CLAIMS 1-5 AND 7-13 (DOUBLE PATENTING)

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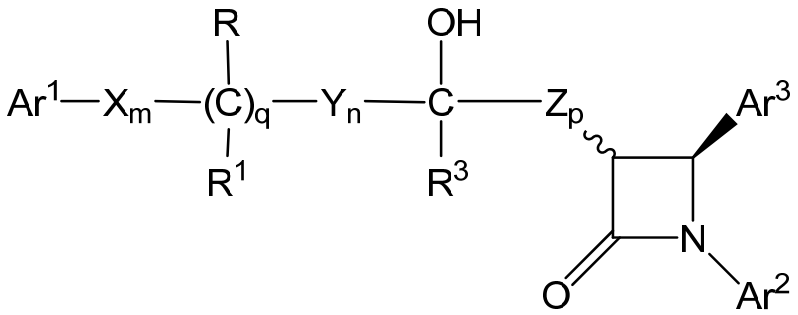
Defendants Glenmark Generics Inc., USA (formerly Glenmark Pharmaceuticals Inc., USA) and Glenmark Pharmaceuticals Ltd. (collectively, "Glenmark") respectfully submit this statement of material facts that are not in dispute in support of its Motion for Summary Judgment of Claims 1-5 and 7-13 (Double Patenting). All exhibits are to the declaration of George Hykal submitted in support of this motion.

1. U.S. Patent No. 5,631,365 ("the '365 patent") includes four claims directed to methods of preparing azetidinone compounds. (Ex. A , SPZ000332072-73).

2. The method recited in claim 1 includes the steps of (a) treating a lactone compound with a strong base, (b) reacting the product of step (a) with an imine, (c) quenching the reaction with an acid, and (d) removing, as necessary, a protecting group. (*Id*. at SPZ000332072).

3. Claim 2 depends from claim 1 and further includes a step of converting a hydroxy or amino substituent on the azetidinone compound to one of a group of other chemical moieties. (*Id*.).

4. The azetidinone compounds formed by the method recited in claims 1 and 2 have the formula shown below.

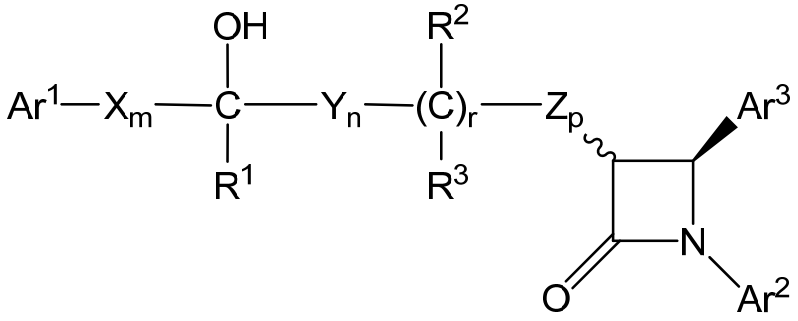


Id.

5. The method recited in claim 3 includes the steps of (a) treating a lactone compound with a strong base, (b) reacting the product of step (a) with an imine, (c) quenching the reaction with an acid, and (d) removing, as necessary, a protecting group.

6. Claim 4 depends from claim 3 and further includes a step of converting a hydroxy or amino substituent on the azetidinone compound to one of a group of other chemical moieties. (*Id.*).

7. The azetidinone compounds formed by the method recited in claims 3 and 4 have the formula shown below.



Id.

8. The '365 patent states that the azetidinone compounds are useful as hypcholesterolemic agents and to treat or prevent atherosclerosis and reduce serum cholesterol levels (*see, e.g.*, *Id.* at SPZ000332053-54, col. 1, lines 9-14, col. 2, line 15, col. 3, lines 33-38).

9. The '365 patent was filed as U.S. Serial No. 08/257,593 ("the '593 application") on June 9, 1994. (Ex. B, SPZ000000452).

10. Page 39 of the '593 application included the following data from a hamster assay. (*Id.* at SPZ000000493)

	% Reduction				% Reduction		
Ex. #	Serum Cholest.	Cholest. Esters	Dose mg/kg	Ex. #	Serum Cholest.	Cholest. Esters	Dose mg/kg
1A	-23	0	50	4C	-12.5	0	3
1B	-15	-39	50	4D	9	0	7
1C	14	0	50	4E	0	-46	3
2	0	0	50	4F	-29	-95	3
3A	-31	-69	50	5	0	-64	10
3C	-60	-92	50	6A	-59	-95	1
3D	-17	-61	10	6B	-40	-92	3
3E	0	0	10	6C	0	-48	3
3F	-29	-77	10	6D	-46	-95	10
3G	-16	-38	10	8A	0	-44	3
3H	-41	-86	10	8B	-50	-95	3
3I	0	-22	10	8C	-14	-37	1
3J	0	0	3	8D	-49	-98	1
3K	0	0	10	8E	-22	-66	3
4A	0	-54	5	8F	-43	-94	1
4B	-37	-89	8	10	-26	-77	3

Id.

11. Compound 6A of the ‘365 Patent is ezetimibe. (Ex. A, SPZ000332069, col. 33, lines 14-20).

12. The November 21, 1994 Office Action in the ‘593 application stated:

> Restriction to one of the following inventions is required under 35 U.S.C. §121:
>
> I. Claims 1-15, drawn to compounds and simple compositions, …
>
> II. Claims 16-24, drawn to complex compositions and kit, …
>
> III. Claims 25-32, drawn to synthesis …
>
> During a telephone conversation with [Schering’s Attorney] Magatti on 11/7/94 a provisional election was made without traverse to prosecute the invention of III, claims 25-32.

(*Id*. at SPZ000000525-530).

13. Claims 1-24 of the '593 application were canceled in a February 21, 1995 amendment. (*Id.* at SPZ000000534-541).

14. In an October 2, 1995 Office Action in the '593 application, the then pending claims 25, 27, 29, and 31 were rejected for lacking enablement under 35 U.S.C. §112, ¶ 1. (*Id.* at SPZ000000576-577). The Patent Examiner stated:

> Claims 25, 27, 29, [and] 31 are rejected [under] 35 USC 112, paragraph 1, for lack of enablement. The compounds are alleged to lower serum cholesterol. Yet applicant's own evidence is that, by and large, they do not. The page 29 data can be summarized as follows:
>
> No reduction (0%) or actually raises level: 12
> Doubtful efficacy (1-24%): 7
> Effective (25+%): 13
>
> Claims must be limited to species which are enabled, In re Harwood, 156 USPQ 673. The preparation of compounds with no utility itself lacks utility, Breenen [sic: Brenner] vs Manson, 148 USPQ 693.

(*Id.* at SPZ000000577).

15. In a November 30, 1995 response filed in the '593 application, Schering argued that:

> Applicants respectfully submit that the compounds prepared by the instantly claimed processes are shown in the specification to have utility. …
>
> The data provided on page 39 [of the specification] demonstrates that compounds made by the claimed process lower cholesterol esters.
>
> … Applicants respectfully submit that the data on page 39 of the specification showing decreases in serum cholesterol and cholesterol esters are sufficient to support the utility of the compounds as hypcholesterolemic agents, and therefore a process for preparing a genus of related compounds is enabled.

(*Id*. at SPZ000000578, 579, 581).

16. In a May 8, 1996 response filed in the '593 application, Schering argued:

> Data provided in the instant specification on page 39 demonstrate that the compounds made by the claimed process reduce hepatic cholesterol ester levels, therefore reducing cholesterol absorption and consequently reducing serum cholesterol.

(*Id.* at SPZ000000591).

17. Schering submitted a declaration dated May 8, 1996 in the '593 application in which Harry R. Davis, Ph.D., stated:

> The subject patent application states on page 22, lines 4 to 12, that the compounds made by the process claimed in the application inhibit intestinal absorption of cholesterol and reduce the formation of liver (hepatic) cholesterol esters, and data showing reduction of cholesterol esters is shown on page 39; one skilled in the art will recognize, therefore, that compounds made by the process of this invention will lower serum cholesterol.

(*Id.* at SPZ000000597).

18. After submission of the May 8, 1996 response and declaration of Harry R. Davis, Ph.D., the '593 application was allowed by the Patent Office. (*Id.* at SPZ000000604-605).

19. The '593 application issued as the '365 patent on May 20, 1997. (Ex. A, SPZ000332052).

20. The '365 patent will expire on May 20, 2014.

21. On September 14, 1994, Schering filed an International application (PCT/US94/10099) which was a continuation-in-part application of the '593 application. (Ex. C, p. 1).

22. In its request for a patent term extension of U.S. Patent No. Re. 37,721 ("the '721 patent"), Schering represented that "[a]t least claims 1, 2, 3, 5, and 7-13 of [the'721 patent] read on … Zetia (ezetimibe) Tablets for the approved indications." (Ex. H at 6-7; *see also id.* at 7-13).

23. The International application entered the U.S. national phase and matured into U.S. Patent No. 5,767,115 ("the '115 patent"). (Ex. D, SPZ000327575, -576, col. 1, lines 5-8).

24. On June 15, 2000, Schering filed reissue application 09/594,996, which issued as the '721 patent on May 28, 2002. (Ex. E, SPZ000000001).

25. The '721 Patent contains both the original claims 1-9 (from the '115 patent) and new claims 10-13. (Compare Ex. D, SPZ000327594-595 with Ex. E, SPZ000000021-022).

26. Independent claim 1 of the '721 patent claims a genus of azetidinone compounds. (*Id.* at SPZ000000021).

27. The genus of azetidinone compounds claimed in claim 1 of the '721 patent encompasses all of the azetidinone compounds which can be prepared by the processes claimed in the '365 patent, except for (i) the compounds in claims 1 and 2 of the '365 patent where the sum of the variables m, n, p, and q is 6 and (ii) the compounds in claims 3 and 4 of the '365 patent where the sum of the variables m, n, p, and r is 6. (Compare EX. E, SPZ000000021 with Ex. A, SPZ000332072-73).

28. Claims 2-5 of the '721 patent depend from claim 1 and further narrow the genus. (Ex. E, SPZ000000021).

29. Each of claims 1-5 of the '721 patent encompasses ezetimibe. (*Id.*).

30. Claim 7 of the '721 patent is an independent claim reciting twenty-four compounds, including ezetimibe. (*Id.* at SPZ000000021-022).

31. Claim 8 of the '721 patent recites a pharmaceutical composition comprising an effective amount of a compound of claim 1 in a pharmaceutically acceptable carrier. (*Id.* at SPZ000000022).

32. Claim 9 of the '721 patent recites a method of treating or preventing atherosclerosis or reducing plasma cholesterol levels by administering to a mammal in need of such treatment an effective amount of claim 1. (*Id.*).

33. Claim 10 of the ‘721 Patent claims ezetimibe and pharmaceutically acceptable salts thereof. (*Id.*)

34. Claim 11 claims ezetimibe.

35. Claims 12 and 13 of the ‘721 Patent are identical to claims 8 and 9 of the ‘721 patent but depend from claim 10 or 11. (*Id.*).

36. The ‘721 patent issued on May 28, 2002. (*Id.* at SPZ000000001).

37. The original expiration date of the ‘721 patent was June 16, 2015.

38. Schering obtained a patent term extension of 497 days, which extends the term of the ‘721 patent to October 25, 2016. (Ex. F).

Dated: July 8, 2009

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